REMARKS

Claim 21 is Supported by Specification and Drawings

The Examiner rejected Claim 21 and the claims that depend therefrom under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner contends, "there is no support for the permanent maintenance of a first lumen distal opening at a position distal of a second distal opening." (Office Action, p. 3). Applicants respectfully traverse the Examiner's rejection, and contend that the entire claim is clearly supported by the specification and drawings.

The Examiner contends that Figures 3 and 4 are not adequate support for depicting "permanent maintenance of an object in position relative to another." Instead, the Examiner states, "such depiction requires 'snapshots' of the relative positions over time, which one drawing cannot provide." (Office Action, p. 2). Applicants can understand the Examiner's concerns. Thus, Applicants refer the Examiner to Figures 3-7 which, as stated in ¶ [0039], "show an operational example of an embodiment of the present device 20 being used to close a wound W in internal bodily tissue."

- Figure 3 shows the device as the patch 60 is attached to the inner lumen distal tip 36 (¶ [0040])
- Figure 4 shows the device as "the patch 60 is advanced to cover and apply pressure to the wound" (¶ [0041])
- Figure 4a shows the device as irrigating fluid F irrigates the field 80 about the wound (¶ [0044])
- Figure 5 shows the device as adhesive A is applied through the space 52 between the inner lumen distal tip 36 and the main body distal tip 44 (¶ [0045])
- Figure 6 shows the device as it is being withdrawn (¶ [0048])
- Figure 7 simply shows the patch on the vessel, but Figure 7a shows an embodiment in which the device, with patch, is advanced through a trocar 92 for endoscopic use (¶ [0054])

Importantly, as shown in these figures, **in every stage of operation inner lumen distal tip 36 is distal of the main body distal tip 44**, and the space 52 is maintained between them. Thus, the figures and text teach an embodiment in which **this relationship is maintained** as the patch is

applied, as the device is advanced onto the wound, while additional operations are performed with the device held in place on the wound, and while the device is being withdrawn from the wound. Since the relationship is maintained during **ALL stages of use**, Applicants contend that there is little doubt that Applicants were in possession of a device in which "the first distal opening is permanently maintained at a position distal of the second distal opening".

Further, Paragraphs [0034] and [0035] of Applicants' specification, which reference Figures 1 and 2, initially describe structure of the illustrated embodiment. The tubular main body 22 is introduced, as well as a first neck 24, which "extends from the proximal end 26 of the tubular main body 22 and terminates in a first connector 28." Further, "An inner lumen 30 extends from the proximal tip 34 of the first connector 28 through the first neck 24 and the main body 22 and terminates at a distal tip 36." Still further, "The inner lumen distal tip 36 extends a short distance beyond the main body distal tip 44 and a space 52 is defined between the outer lumen distal opening 50 and the inner lumen distal opening 40." If the inner lumen were movable proximally so that the inner lumen distal tip 36 were proximal the main body distal tip 44, then the other end of the inner lumen 30 would be distal of the proximal tip 34 of the first connector 28. This would *defeat the structure of the first connector*, and make the first connector inoperable. It is unreasonable to interpret the specification as teaching such an inoperable embodiment. Rather, it is reasonable to interpret the specification to teach an *operable* embodiment in which the inner lumen 30 maintains its position relative to the first connector 28 so that the first connector remains operable. As such, the specification in its present form, when interpreted to maintain the operability of the illustrated embodiment, clearly supports an embodiment in which *the position of the inner lumen 30 is maintained relative to the first connector 28*. Maintaining such position would of necessity mean that the inner lumen distal tip 36 would be *permanently distal of the main body distal tip 44*. As such, this embodiment supports the language of Claim 21.

In light of the above discussion, Applicants contend that there is ample support in the specification as originally filed to support the Claim 21 limitation "the first distal opening is permanently maintained at a position distal of the second distal opening". Applicants thus respectfully request that the Examiner withdraw the §112 rejection of Claim 21 and the claims that depend therfrom.

Claim 35 is Supported by Specification and Drawings

The Examiner also rejected Claim 35 under 35 U.S.C. § 112, first paragraph, contending that there is no "explicit support for the limitation that the diameter of the wound cover is greater than the diameter of the second lumen." Claim 35 has been amended to clarify that the maximum diameter of the wound cover is greater than a diameter of the second lumen distal opening. This is clearly supported at least by Figures 3-6 and 7a, in which a maximum diameter of the wound cover is visibly greater than the diameter of the second lumen distal opening. Accordingly, Applicants respectfully request that the Examiner withdraw the §112 rejection of Claim 35.

Cited Reference

The Examiner rejected the claims under 35 U.S.C. § 102(b) as anticipated by Hammerslag ('194). Applicants respectfully traverse the rejection.

The Examiner states that in Hammerslag "the first and second portions are rigidly connected to one another so as to always move as a single elongate unit (Col. 13, lines 62-67, Col. 14, lines 1-5)". (Office Action, p. 3). The lines of Hammerslag cited by the Examiner read:

> At the point in the procedure illustrated at FIG. 10, the site is prepared for the application of an adhesive patch 88. Patch 88 is preferably secured to a patch applicator 80, as has been previously discussed. Attachment of the patch 88 to the applicator 80 can be accomplished such as through the use of a relatively weak adhesive bond or mechanical interfitting. In one embodiment, the patch 88 is preassembled onto the applicator 80, such as at the point of manufacture, by placing a relatively short shipping guidewire through the patch and into the guidewire lumen of applicator 80. This shipping guidewire may be provided with a distal anchor, ... (Col. 13, ll. 62-67, Col. 14, ll. 1-5)

If the above passage (and/or FIG. 10) supports the Examiner's contention about the first and second portions being rigidly connected, Applicants respectfully request that the Examiner explain how.

Applicants note that Col 13, ll. 56-60 states, "the function of introducer cannula 270 can be readily accomplished by a structure integrally formed or secured to the applicator 80." However, it goes on to clarify, "For example, the delivery surface 86 can be **retractably**

disposed within an outer tubular housing." (emphasis added). Thus, this doesn't appear to support the Examiner's contention either.

Conclusion

Applicants respectfully submit that the rejections and objections set forth in the outstanding Office Action are inapplicable to the present claims and specification. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections and objections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

Respectfully submitted,

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